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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,666	03/08/2006	Vincent Fischetti	600-1-295PCTUS	2384

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EXAMINER	
MARX, IRENE	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
04/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,666	FISCHETTI ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,23,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17, 23 and 30-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 2/16/10 is acknowledged. Claims 17, 23 and 30-31 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 23 and 30-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for "wherein Pal and Cpl-1 are present at 0.5 minimal inhibitory concentration (MIC) or less and the combination demonstrates a bacterial titer reduction of ≥ 2 $\log_{10}$ greater than the single Pal or Cpl-1 agents." It is not apparent that an open-ended or infinite bacterial titer reduction is disclosed.

No basis or support is found in the present specification the recitation of "comprising a mixture of Pal and Cpl-1 at a concentration of 0.5 U/ml wherein the killing efficacy of the mixture is increased by greater than 1 $\log_{10}$ compared to 1 U/ml of Pal or Cpl-1 alone as in claims 30 and 31." It is noted that the "killing efficacy" target is not disclosed. Also, it is not apparent that an open-ended or infinite "killing efficacy" is disclosed.

No clear basis or support is found in the present specification for the recitation of "anti pneumococcal lytic enzyme" with respect to Pal or Cpl-1.

Therefore, this material constitutes new matter and should be deleted.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant pointed to certain portions of the specification as providing basis or support. However, there is no clear correlation between the cited paragraphs and drawings and the invention as now claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 23 lack antecedent basis for "demonstrates a bacterial titer reduction", since the bacteria are not identified with particularity. Moreover, the concentration of the "single Pal or Cpl-1 agents" is not identified. In addition, the phrase "wherein Pal and Cpl-1 are present at 0.5 minimal inhibitory concentration (MIC) or less and the combination demonstrates a bacterial titer reduction of ≥ 2 $\log_{10}$ greater than the single Pal or Cpl-1 agents" does not specify whether 0.5 MIC is for each enzyme or for both together. Thus the amount is undefined. Also, claims 17 and 23 are vague, indefinite, inconsistent and contradictory in the recitation of" ≥ 2 $\log_{10}$ greater …" . It is unclear what is intended.

In claims 30 and 31, the phrase "comprising a mixture of Pal and Cpl-1 at a concentration of 0.5 U/ml wherein the killing efficacy of the mixture is increased by greater than 1 $\log_{10}$ compared to 1 U/ml of Pal or Cpl-1 alone" does not specify whether 0.5 U/ml pertains to each enzyme or to both together. Thus the amount is undefined Claims 30 and 31 are also vague and confusing in that the target of the killing efficacy is not disclosed.

The claims are confusing in the recitation of "anti pneumococcal lytic enzyme" with respect to Pal or Cpl-1."

Claim Rejections - 35 USC § 103

Claims 17 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischetti *et al.* (I)(U.S. Patent No. 6,264,945) taken with Marova *et al.* (Folia Microbiol. 38 (3), 245- 252 (1993)), Fischetti *et al.* (II)(U.S. Patent No. 6,056,954), Sanz *et al.* (Eur. J. Biochem. 187,409-416 (1990)) and Loeffler *et al.* (Science **294:**2170-2172).

The claims are directed to a composition comprising bacteriophage derived lytic enzymes Cpt-1 and Pal having a certain desired effect.

Fischetti *et al.* (I) teach a composition comprising at least two lytic enzymes which are an amidase and a muramidase. See, e.g., col. 7, lines 9-25, wherein it is taught that a phage lysin is combined with lysostaphin. It is noted that lysostaphin is an amidase that comprises hexosaminidase (N-acetylglucosaminidase), glycylglycine-endopeptidase and N-acetylmuramyl-L-alanine-**amidase**, as demonstrated by Marova *et al.* (See, e.g., page 245, paragraph 2).

The composition of Fischetti *et al.* differs from the claimed composition in that it is not specifically indicated as being solely "bacteriophage obtained" and in comprising Pal and Cpl-1.

However, Fischetti *et al.* (II) strongly suggests the use of several bacteriophage lytic enzymes in combination. See, e.g., col. 13, lines 16-25.

In addition, Loeffler *et al.* teach the favorable properties of the cell wall degrading enzyme Pal, while Sanz *et al.* teach the favorable properties of Cpl-1 lysozyme. The references indicate that both enzymes are active on the dangerous pathogen *P. pneumoniae*. See, e.g., respective Abstracts and Loeffler *et al.,* page 270, paragraph 1; Sanz *et al.,* page 410, paragraph 5. Therefore, one of ordinary skill in the art would have included them at the time the claimed invention was made in an anti-pneumococcal or antimicrobial composition with a reasonable expectation of success.

One of ordinary skill in the art would have had a compelling motivation in providing a combination of various bacteriophage derived enzymes as taught by Fischetti *et al.* (II) and/or replacing the lysostaphin degradative enzymes in the composition of Fischetti *et al.* (I) with bacteriophage derived enzymes having the same or similar degradative activity, such as Pal and Cpl-1 for their recognized beneficial properties that include specificity for certain dangerous pathogenic bacteria including *S. pneumoniae* as well as stability.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition of Fischetti *et al.* (I) by replacing the degradative enzymes therein with bacteriophage derived degradative enzymes as taught by Fischetti *et al.* (II) in particular Pal and Cpl-1 as suggested by the teachings of Loeffler *et al.* and Sanz *et al.* for the expected benefit of providing anti-microbial composition having powerful degradative activity and suitable for the control of the dangerous and resistant bacterial pathogen *.P. pneumoniae.*

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the instant claims are directed to compositions comprising "particular and disclosed" amounts of bacteriophage derived lytic enzymes having a certain desired effect.

However, the claimed invention of claims 17 and 23 fails to disclose whether each of the enzymes is present at 0.5 MIC or less, or, if the amount pertains to the combination, the contribution of each enzyme to the claimed composition. In addition, it is well know that the minimal inhibitory concentration depends on the strain treated. Applicant directs the invention to "a bacterial titer reduction" without an indication of the bacterial strain intended or even whether the comparison pertains to the same strain in each instance.

Regarding claims 30 and 31, the claims are directed to "killing efficacy" in the comparison without an indication of the target or whether the identical target is used in the comparison. As to the amount of 0.5 U/ml, applicant does not indicate with any specificity whether it pertains to each enzyme or to both together.

Therefore, the claimed invention fails to be directed to "compositions comprising particular and disclosed amounts of bacteriophage derived lytic enzymes having a certain desired effect" as alleged..

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651